

**CLAIM AMENDMENTS**

This listing of claims will replace all prior versions, and listings, of claims in the application

---

1. (Previously presented) A method of preparing homogeneous microparticles comprising a pharmaceutically active substance, wherein the method uses a spray freezing technique and comprises the steps of:

a) atomizing into droplets a liquid medium having a minimum dry content of 15 % by volume and comprising:

- B1*
- i) a pharmaceutically active substance;
  - ii) a polymer selected from the group consisting of water soluble polymers and non -water soluble polymers, said polymer being present in an amount of at least 5 per cent by weight based upon the dry content of the medium;
  - iii) a liquid in which the pharmaceutically active substance and polymer are suspended, dissolved or emulsified; and
  - iv) optionally a dispersing agent;

b) freezing the formed droplets; and

c) sublimating the frozen liquid of the droplets to obtain dry, homogeneous microparticles.

2. (Previously presented) The method according to claim 1, wherein the polymer of the liquid medium constitutes at least 10 weight % of the dry content.

3. (Previously presented) The method according to claim 1, wherein the polymer of the liquid medium constitutes at least 15 weight % of the dry content.

4. (Previously presented) The method according to claim 1, wherein the dry content of the liquid medium is from 15 to 60 vol %.

5. (Previously presented) The method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a relative density of 15 to 60 %.

6. (Previously presented) The method according to claim 1, wherein the dry volume content of the liquid medium is from 15 to 60 vol % and gives dry microparticles with a porosity of 40 to 85 vol %.

*B1 cont*  
7. (Previously presented) The method according to claim 1, wherein the liquid medium to be spray-frozen is a suspension.

8. (Previously presented) The method according to claim 1, wherein the liquid medium to be spray-frozen is a solution.

9. (Previously presented) The method according to claim 1, wherein the liquid medium to be spray-frozen is an emulsion.

10. (Previously presented) The method according to any one of claims 1-9, wherein the content of the pharmaceutically active substance is from 60 to 95 weight % of the weight of the dried microparticles.

11. (Previously presented) The method according to any one of claims 1-9, wherein the dry content of the medium is from 15 to 60 vol % and the content of the pharmaceutically active substance is from 60 to 95 weight % of the dried microparticles.

12. (Previously presented) The method according to any one of claims 1-9, wherein the polymer and dispersing agent are selected from the group consisting of cellulose derivatives, polysaccharides, natural polymers, synthetic polymers, surfactants, and mixtures thereof.

13. (Previously presented) The method according to any one of claims 1-9, wherein the polymer and dispersing agent are selected from the group consisting of shellacs, waxes, nylon, stearates, lipids, paraffin, lignosulphonates, and mixtures thereof.

14. (Currently amended) The method according to any one of claims 1-9, wherein the liquid in which the polymer is suspended, dissolved or emulsified ~~[[soluble]]~~ is selected from the group consisting of water, tertiary butyl alcohol, cyclohexane, methylene chloride, methanol, ethanol, and mixtures thereof.

15. (Previously presented) The method according to any one of claims 1-9, wherein the formed droplets are frozen by a cold medium selected from the group consisting of liquid nitrogen, liquid argon, liquid oxygen, and solvents cooled below the freezing point of the liquid in the suspension.

16. (Previously presented) The method according to any one of claims 1-9, wherein the sublimation is performed by freeze-drying.

17. (Previously presented) The method according to any one of claims 1-9, wherein the size distribution of the prepared microparticles is in the range from 10 to 1000  $\mu\text{m}$ .

18. (Previously presented) Microparticles prepared according to the method of any one of claims 1-9.

Serial No. 09/674,043, filed Oct. 23, 2000

Docket No. 1103326-0642

Page 5 of 14

19. (Original) The microparticles according to claim 18 further comprising a polymeric film coating.

20. (Previously presented) The method according to any one of claims 1-9, further comprising the step of coating the microparticles with a polymeric film coating.

*B1  
conced*  
21. (Previously presented) The method according to any one of claims 1-9, wherein the content of the pharmaceutically active substance is from 75 to 90 weight % of the weight of the dried microparticles.

22. (Previously presented) The method according to any one of claims 1-9, wherein the liquid medium further comprises one or more plasticizers.

23. (Previously presented) The method according to claim 22, wherein the plasticizer is selected from the group consisting of glycerin, polyethylene glycol, propylene glycol, triethyl citrate, diethyl phthalate, dibutyl phthalate, dibutyl sebacate, sorbitol, tiacetin, and mixtures thereof.

---